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PATENTS  
Attorney Docket No. TNA-005.05

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
Hing C. Wong et al. )  
Application No: 10/764,140 ) Art Unit: 1645  
Filed: January 22, 2004 ) Confirmation No.: 6085  
For: ANTIBODIES FOR INHIBITING ) Examiner: Not yet known  
BLOOD COAGULATION AND )  
METHODS OF USE THEREOF )

**CERTIFICATE OF MAILING/TRANSMISSION**

I hereby certify that the correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 19, 2006.

*Shirine Darvish*

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Mail Stop Amendment  
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Sir:

**SUPPLEMENTAL INFORMATION-DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. § 1.97 (b)(3)**

Applicants hereby bring to the Examiner's attention the references listed on the accompanying form PTO-1449 in compliance with the requirements of 37 C.F.R. §§ 1.56 and 1.97(b)(3). Pursuant to 37 C.F.R. § 1.98 (2)(i), Applicants have not enclosed copies of the cited U.S. patents or publications. Copies of the documents (References DF-FI) identified in the Form PTO-1449 are not provided because they were previously cited by or submitted to the Patent Office in the prior parent patent application, USSN 10/618,338, which was filed July 11, 2003; therefore, they are not required to be provided in this application. However, Applicants will gladly furnish copies of some or all of same upon request.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

Applicants have listed dates of publication on the attached PTO-1449 for the cited documents based on information presently available to the undersigned. However, the listed publication dates should not be construed that the information in the cited documents was actually published or otherwise publicly available on the date indicated.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that each or all of the listed documents are material or constitute "prior art." Further, if the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Moreover, the Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

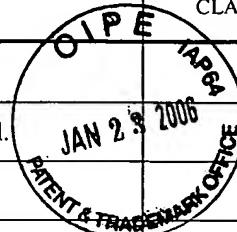
Under 37 C.F.R. § 1.97 (b)(3), this Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits; therefore, no fee is believed to be due in connection with this submission. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, the Commissioner is authorized to charge any deficiencies or credit any overpayment to our **Deposit Account, No. 06-1448, Reference TNA-005.05.**

Respectfully submitted,

Date: January 19, 2006  
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Form PTO-1449 <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> <i>(Use several sheets if necessary)</i>				Docket Number (Optional) <b>TNA-005.05</b>	Application Number <b>10/764,140</b>		
				Applicant <b>Hing C. Wong et al.</b>			
				Filing Date <b>January 22, 2004</b>	Group Art Unit <b>1645</b>		
				<b>U.S. PATENT DOCUMENTS</b>			
EXAMINER INITIAL	DOCUMENT NUMBER		DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BJ	2003/0109680	06/12/03	Jiao et al.			
	BK	2003/0082636	09/18/03	Wong et al.			
	BL	2003/0176664	09/18/03	Jiao et al.			
	BM	2005/0089929	04/28/05	Jiao et al.			
	BN	5,589,173	12/31/96	O'Brien et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
	DOCUMENT NUMBER		DATE	COUNTRY	CLASS	SUBCLASS	Translation YES      NO
<b>OTHER DOCUMENTS</b> <i>(Including Author, Title, Date, Pertinent Pages Etc.)</i>							
	DF	Albrecht et al., "An ELISA for tissue factor using monoclonal antibodies," Blood Coagulation and Fibrinolysis, 3:263-270 (1992)					
	DG	Almus et al., "Properties of Factor VIIa/Tissue Factor Complexes in an Umbilical Vein Model," Blood, 76(2):354-360 (1990)					
	DH	Ardaillou et al., "Glomerular tissue factor stimulates thromboxane synthesis in human platelets via thrombin generation," Kidney International, 41:361-368 (1992)					
	DI	Barstad et al., "Procoagulant Human Monocytes Mediate Tissue Factor/Factor VIIa-Dependent Platelet-Thrombus Formation When Exposed to Flowing Nonanticoagulated Human Blood," Arteriosclerosis, Thrombosis, and Vascular Biology, 15(1):11-16 (1995)					
	DJ	Beers et al., The Merck Manual of Diagnosis and Therapy, 17 <sup>th</sup> edition, 1999, Merck Research Laboratories, pps. 1654-1681					
	DK	Benedict et al., "Monoclonal Antibody to Tissue Factor Inhibits Intravascular Thrombosis without Impairing Extravascular Hemostasis," JACC, February 1995 Abstract 1012-104, p. 366A					
	DL	Bjoern et al., "Human Plasma and Recombinant Factor VII," The Journal of Biological Chemistry, 266(17):11051-11057 (1991)					
	DM	Broze, George J., Jr., "Binding of Human Factor VII and VIIa to Monocytes," J. Clin. Invest. The American Society for Clinical Investigation, Inc., 70:526-535 (1982)					
	DN	Carson et al., "An Inhibitory Monoclonal Antibody Against Human Tissue Factor," Blood, 70(2):490-493 (1987)					



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	DO	Carson et al., "Monoclonal Antibodies Against Bovine Tissue Factor, Which Block Interaction With Factor VII," Blood, 66(1):152-156 (1985)		
	DP	Cate et al., "The Activation of Factor X and Prothrombin by Recombinant Factor VIIa in Vivo Is Mediated by Tissue Factor," The Journal of Clinical Investigation, Inc., 92:1207-1212 (1993)		
	DQ	Chapman et al., "Regulation of the Procoagulant Activity within the Bronchoalveolar Compartment of Normal Human Lung," Am. Rev. Respir. Dis., 137(6):1417-1425 (1988)		
	DR	Chattopadhyay et al., "Molecular Recognition Sites on Factor Xa Which Participate in the Prothrombinase Complex," The Journal of Biological Chemistry, 267(17):12323-12329 (1992)		
	DS	Clarke et al., "The first epidermal growth factor domain of human coagulation factor VII is essential for binding with tissue factor," Federation of European Biochemical Societies, 298(2,3):206-310 (1992)		
	DT	Collen et al., "New thrombolytic agents and strategies," Bailliere's Clinical Haematology, 8(2):425-435 (1995)		
	DU	Colman, P.M., "Effects of amino acid sequence changes on antibody-antigen interactions," Research in Immunology, 145:33-36 (1994)		
	DV	Contrino et al., "In Situ Characterization of Antigenic and Functional Tissue Factor Expression in Human Tumors Utilizing Monoclonal Antibodies and Recombinant Factor VIIa as Probes," American Journal of Pathology, 145(6):1315-1322 (1994)		
	DW	Drake et al., "Functional Tissue Factor Is Entirely Cell Surface Expressed on Lipopolysaccharide-stimulated Human Blood Monocytes and a Constitutively Tissue Factor-producing Neoplastic Cell Line," The Journal of Cell Biology, 109:389-395 (1989)		
	DX	Drake et al., "Selective Cellular Expression of Tissue Factor in Human Tissues," American Journal of Pathology, 134(5):1087-1097 (1989)		
	DY	Fair et al., Cooperative Interaction Between Factor VII and Cell Surface-Expressed Tissue Factor, The Journal of Biological Chemistry, Vol. 262, August 25, 1987, pp. 11692-11698		
	DZ	Faulk et al., "Tissue Factor: Identification and Characterization of Cell Types in Human Placentae," Blood, 76(1):86-96 (1990)		
	EA	Fay et al., "Mutating factor VIII: lessons from structure to function," Blood Reviews, 19:15-17 (2005)		
	EB	Flössel et al., "Immunohistochemical detection of tissue factor (TF) on paraffin sections of routinely fixed human tissue," Histochemistry, 101:449-453 (1994)		
	EC	Gouault-Heilmann et al., "The Procoagulant Factor of Leukaemic Promyelocytes: Demonstration of Immunologic Cross Reactivity with Human Brain Tissue Factor," British Journal of Haematology, 30:151-158 (1975)		
	ED	Grabowski et al., "The Functional Expression of Tissue Factor by Fibroblasts and Endothelial Cells Under Flow Conditions," Blood, 81(2):3265-3270 (1993)		
	EE	Hamaguchi et al., "FDP D-Dimer Induces the Secretion of Interleukin-1, Urokinase-Type Plasminogen Activator, and Plasminogen Activator Inhibitor-2 in a Human Promonocytic Leukemia Cell Line," Blood, 77(1):94-100 (1991)		

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	EF	Hoffman et al., "Human Monocytes Support Factor X Activation by Factor VIIa, Independent of Tissue Factor: Implications for the Therapeutic Mechanism of High-Dose Factor VIIa in Hemophilia," <i>Blood</i> , 83(1):38-42 (1994)		
	EG	Huang et al., "The Mechanism of an Inhibitory Antibody on TF-initiated Blood Coagulation Revealed by the Crystal Structures of Human Tissue Factor, Fab 5G9 and TF 5G9 Complex," <i>J. Mol. Biol.</i> , 275:873-894 (1998)		
	EH	Imamura et al., "Role of Macrophage Tissue Factor in the Development of the Delayed Hypersensitivity Reaction in Monkey Skin," <i>Cellular Immunology</i> , 152:614-622 (1993)		
	EI	Ito et al., "Characterization of Functionally Important Regions of Tissue Factor by Using Monoclonal Antibodies," <i>J. Biochem.</i> , 114(5):691-696 (1993)		
	EJ	James et al., "Inhibition of tissue factor activity reduces the density of cellular network formation in an in vitro model of angiogenesis," <i>Biochemical Society Transactions</i> , 30(2):217-221 (2002)		
	EK	Jang et al., "Antithrombotic Effect of a Monoclonal Antibody Against Tissue Factor in a Rabbit Model of Platelet-Mediated Arterial Thrombosis," <i>Arteriosclerosis and Thrombosis</i> , 12(8):948-954 (1992)		
	EL	Kirchhofer et al., "The Tissue Factor Region That Interacts with Factor Xa in the Activation of Factor VII," <i>Biochemistry</i> , 40:675-682 (2001)		
	EM	Kumar et al., "Identification of Molecular Sites on Factor VII Which Mediate Its Assembly and Function in the Extrinsic Pathway Activation Complex," <i>The Journal of Biological Chemistry</i> , 266(2):915-921 (1991)		
	EN	Kumar et al., "Specific molecular interaction sites on factor VII involved in factor X activation," <i>Eur. J. Biochem.</i> 217:509-518 (1993)		
	EO	Levi et al., "Inhibition of Endotoxin-induced Activation of Coagulation and Fibrinolysis by Pentoxifylline or by a Monoclonal Anti-tissue factor Antibody in Chimpanzees," <i>The Journal of Clinical Investigation, Inc.</i> , 93:114-120 (1994)		
	EP	Maekawa et al., "Complement-Dependent Immunosuppressive Anti-Tissue Factor Monoclonal Antibody: The Establishment of Monoclonal Antibodies and Their Effect on Mixed Lymphocyte Reaction," <i>Transplantation Proceedings</i> , 25(4):2713-2715 (1993)		
	EQ	Martin et al., Activation of Factor X by Factor VIIa on Monocyte Cell Surfaces, pp. 3828 – 3829 <i>Blood</i> . 1994 Jun 15;83(12):3828-9.		
	ER	Martin et al., "Tissue Factor: molecular recognition and cofactor function," <i>The FASEB Journal</i> , 9:852-859 (1995)		
	ES	Masuda et al., "Association of tissue factor with a γ chain homodimer of the IgE receptor type I in cultured human monocytes," <i>Eur. J. Immunol.</i> , 26:2529-2532 (1996)		
	ET	McGee et al., "Functional Difference between Intrinsic and Extrinsic Coagulation Pathways," <i>The Journal of Biological Chemistry</i> , 266(13):8079-8085 (1991)		
	EU	Merriam-Webster Online dictionary, downloaded October 11, 2005, world wide web at m-w.com, definition of thrombosis, 2 pages		
	EV	Morrissey et al., "Monoclonal Antibody Analysis of Purified and Cell-Associated Tissue Factor," <i>Thrombosis Research</i> , 52:247-261 (1988)		

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	EW	Morrissey et al., "Resolution of Monomeric and Heterodimeric Forms of Tissue Factor, the High-Affinity Cellular Receptor for Factor VII," <i>Thrombosis Research</i> , 50:481-493 (1988)		
	EX	Mueller, Barbara M., Expression of Tissue Factor by Melanoma Cells Promotes Efficient Hematogenous Metastasis, <i>Proc. Natl. Acad. Sci. USA</i> , December 1992, Vol. 89, pp. 11832-11836		
	EY	Muller et al., "Structure of the Extracellular Domain of Human Tissue Factor: Location of the Factor VIIa Binding Site,"		
	EZ	Nemerson et al., "An Ordered Addition, Essential Activation Model of the Tissue Factor Pathway of Coagulation: Evidence for a Conformational Cage," <i>Biochemistry</i> , 25:4020-4033 (1986)		
	FA	Noguchi et al., "Correlation Between Antigenic and Functional Expression of Tissue Factor on the Surface of Cultured Human Endothelial Cells Following Stimulation by Lipopolysaccharide Endotoxin," <i>Thrombosis Research</i> , 55:87-97 (1989)		
	FB	Østerud et al., "The Interaction of Human Blood Coagulation Factor VII and Tissue Factor: The Effect of Anti Factor VII, Anti Tissue Factor and Diisopropylfluorophosphate," <i>Biochemical and Biophysical Research Communications</i> , 88(1):59-67 (1979)		
	FC	Pawashe et al., A Monoclonal Antibody Against Rabbit Tissue Factor Inhibits Thrombus Formation in Stenotic Injured Rabbit Carotid Arteries, <i>Tissue Factor and Intravascular Thrombosis</i> , January 1994, Vol. 74, No. 1, pp. 56-63		
	FD	Ploplis et al., Initiation of the Extrinsic Pathway of Coagulation – Association of Factor VIIa with a Cell Line Expressing Tissue Factor, <i>The Journal of Biological Chemistry</i> , July 15, 1987, Vol. 262, pp. 9503-9508		
	FE	Price et al., "Tissue factor and tissue factor pathway inhibitor," <i>Anaesthesia</i> , 59:483-492 (2004)		
	EF	Rehemtulla et al., The Integrity of the Cysteine 186-Cysteine 209 Bond of the Second Disulfide Loop of Tissue Factor Is Required for Binding of Factor VII, <i>The Journal of Biological Chemistry</i> , June 5, 1991, Vol. 266, No. 16, pp. 10294-10299		
	EG	Ruf et al., An Anti-Tissue Factor Monoclonal Antibody Which Inhibits TF-VIIa Complex Is a Potent Anticoagulant in Plasma, <i>Thrombosis and Haemostasis</i> , F.K. Schattauer Verlagsgesellschaft mbH (Stuttgart) 66 (5) 529-533 (1991)		
	EH	Ruf et al., Antibody Mapping of Tissue Factor Implicates Two Different Exon-Encoded Regions in Function, <i>Biochem J.</i> (1991) 278, pp. 729-733		
	EI	Ruf et al., Characterization of Factor VII Association with Tissue Factor in Solution – High and Low Affinity Calcium Binding Sites in Factor VII Contribute to Functionally Distinct Interactions, <i>The Journal of Biological Chemistry</i> , Vol. 266, August 25, 1991, pp. 15719-15725		
	EJ	Ruf et al., Phospholipid-independent and –dependent Interactions Required for Tissue Factor Receptor and Cofactor Function, <i>The Journal of Biological Chemistry</i> , February 5, 1991, Vol. 266, pp. 2158-2166		
	EK	Ruf et al., Structural Biology of Tissue Factor, the Initiator of Thrombogenesis in Vivo, <i>The FASEB Journal</i> , April 1994, Vol. 8, pp. 385-390		
	EL	Ruf et al., Tissue Factor Residues 157-167 Are Required for Efficient Proteolytic Activation of Factor X and Factor VII, <i>The Journal of Biological Chemistry</i> , November 5, 1992, Vol. 267, No. 31, pp. 22206-22210		
	EM	Ruf et al., Two Sites in the Tissue Factor Extracellular Domain Mediate the Recognition of the Ligand Factor VIIa, <i>Proc. Natl. Acad. Sci. USA</i> , October 1991, Vol. 88, pp. 8430-8434		

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	EN	Ryan et al., Tumor Necrosis Factor-Induced Endothelial Tissue Factor Is Associated With Subendothelial Matrix Vesicles But Is Not Expressed on the Apical Surface, Blood, August 15, 1992, Vol. 80, No. 4, pp. 966-974		
	EO	Sakai et al., Binding of Human Factors VII and VIIa to a Human Bladder Carcinoma Cell Line (J82) – Implications For The Initiation of the Extrinsic Pathway of Blooad Coagulation, The Journal of Biological Chemistry, Vol. 264, No. 17, June 15, 1989, pp. 9980-9988		
	EP	Salatti et al., Modulation of Procoagulant Activity of Extracellular Endothelial Matrix by Anti-Tissue Factor Antibody and the Synthetic Peptide Arg-Gly-Asp-Val. Experiments with Flowing Non-Anticoagulated Human Blood, Blood Coagulation and Fibrinolysis, 1993, Vol. 4, pp. 881-890		
	EQ	Sandset et al., Immunodepletion of Extrinsic Pathway Inhibitor Sensitizes Rabbits to Endotoxin-Induced Intravascular Coagulation and the Generalized Schwartzman Reaction, Blood, September 15, 1991, Vol. 78, No. 6, pp. 1496-1502		
	ER	Speidel et al. ,Procoagulant Activity on Injured Arteries and Associated Thrombi Is Mediated Primarily by the Complex of Tissue Factor and Factor VIIa, Pathophysiology and Natural History, Coronary Artery Disease, January 1996, Vol. 7, No. 1, pp. 58-62		
	ES	Stephens et al., Production of Tissue Factor By Monocyte Porgenitor Cells, Thrombosis Research, 1994, Vol. 76, No. 1, pp. 33-45		
	ET	Sturm et al., Immunohistological Detection of Tissue Factor in Normal and Abnormal Human Mammary Glands Using Monoclonal Antibodies, Virchows Archiv A Pathological Anatomy and Histopathology, 1992, 421:79-86		
	EU	Toomey et al., Localization of the Hu:nan Tissue Factor Recognition Determinant of Human Factor VIIa, The Journal of Biological Chemistry, October 15, 1991, Vol. 266, No. 29, pp. 19198-19202		
	EV	Tsao et al., Monocytes Can Be Induced by Lipopolysaccharide-Triggered T Lymphocytes To Express Functional Factor VII/VIIa Protease Activity, J. Exp. Med., April 1984, Vol. 159, pp. 1042-1057		
	EW	Tsuda et al., Development of Antitissue Factor Antibodies in Patients After Liver Surgery, Blood, Vol. 82, No. 1 July 1, 1993, pp. 96-102		
	EX	Walsh et al., Discordant Expression of Tissue Factor Antigen and Procoagulant Activity on Human Monocytes Activated with LPS and Low Dose Cycloheximide, Thrombosis and Haemostasis, F.K. Achattauer Verlagsgesellschaft mbH (Stuttgart), 1991, 66 (5), pp. 552-558		
	EY	Warr et al., Disseminated Intravascular Coagulation in Rabbits Induced by Administration of Endotoxin or Tissue Factor: Effect of Anti-Tissue Factor Antibodies and Measurement of Plasma Extrinsic Pathway Inhibitor Activity, Blood, Vol. 75, No. 7, April 1, 1990, pp. 1481-1489		
	EZ	Camerer et al., "Tissue Factor - And Factor X-Dependent Activation of Protease-Activated Receptor 2 by Factor VIIa," PNAS, 97(10):5255-5260 (2000)		
	FA	Ruf et al., "Tissue Factor Signaling," Thrombosis and Haemostasis, 82(2):175-182 (1999)		
	FB	Olivier et al., "Tissue Factor-Dependent Vascular Endothelial Growth Factor Production by Human Fibroblasts in Response to Activated Factor VII," Blood, 91(8):2698-2703 (1998)		
	FC	Wiiger et al., "Effects of Binding of Ligand (FVIIa) to Induced Tissue Factor in Human Endothelial Cells," Thrombosis Research, 98:311-321 (2000)		
	FD	Konigsberg et al., "The TF:VIIa Complex: Clinical Significance, Structure-Function Relationships and Its Role in Signaling and Metastasis," Thrombosis Haemostasis, 86:757-771 (2001)		

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	FE	Riewald et al., "Mechanistic Coupling of Protease Signaling and Initiation of Coagulation by Tissue Factor," PNAS, 98(14):7742-7747 (2001)	
	FF	Mueller et al., "Expression of Tissue Factor by Melanoma Cells Promote Efficient Hematogenous Metastasis," Proc. Natl. Acad. Sci. USA, 89:11832-11836 (1992)	
	FG	Poster Presentation Experimental Biology 2001, March 31-April 4, 2001, Orlando, Florida, Anti-Tissue Factor Antibodies	
	FH	Francis et al., "Effect of Antihemostatic Agents on Experimental Tumor Dissemination," Sem. in Thrombosis and Haemostasis, 28(1):29-38 (2002)	
	FI	Amirkhosravi et al., Suppl. to J. of Thrombosis and Haemostasis Abstract:OC1021 (2001)	